MANAGEMENT OF INVESTIGATIONAL DEVICE PROCEDURES

OBJECTIVE:

a) To outline procedures for management and inventory control of Investigational Devices (IDs) used in approved research protocols at the Atlanta VA Health Care System (AVAHCS).

b) IRB review and approval and investigator conduct of all investigational device studies must be in accordance with all applicable VA, Institutional Review Board of record (IRB), and other requirements. If the research involves FDA-regulated devices, both VA and FDA requirements apply. FDA regulations supersede VA requirements for human subjects research under FDA jurisdiction unless VA requirements are more restrictive than applicable FDA regulations.

PROCEDURES:

a) The Principal Investigator (PI) shall include as part of the application for IRB review a description of the PI's plan for controlling the dispensation, use and disposal of the Investigational Device.

b) Investigational Devices will be administered only to subjects who have agreed to participate in the study and who have signed an Informed Consent Form.

c) If the ID's are shipped to and in the control of the PI, the PI or research staff will record receipt of the device on an Investigational Device Log throughout the study to maintain an accurate inventory and utilization record. Staff may use the Investigational Device Accountability Log located on the AVAHCS research website or another suitable Investigational Device Accountability Log (i.e. the sponsor's), if it includes at a minimum the items listed in section "g" below.

d) The PI or research staff must ensure that the ID package has a label with name/place of manufacturer, distributor and quantity of contents. The label must describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings and precautions.

e) The PI or research staff must store IDs in a secure, locked area specifically designated for research supplies. Do not store IDs with approved devices used in standard medical care.

f) The ID must be administered only to participants under the PI's direct personal supervision or under the supervision of a co-investigator who is directly responsible to the PI.

g) The ID Log should include:
   I. Type and quantity of the device, the dates of receipt, and the batch number or code mark
   II. The names of all persons who received, used, or disposed of each device
   III. Number of units returned to the sponsor, repaired, or otherwise disposed of along with an explanation for each entry.

h) Upon completion or termination of the study, the Investigator shall return any remaining supplies to the sponsor or otherwise dispose of the IDs as instructed by the sponsor.

i) For more information, please contact the AVAHCS Research Office, refer to the IRB of record Policies and Procedures, and applicable FDA regulations.